

**PSORIASIN GEL- coal tar gel**  
**Denison Pharmaceuticals Inc.**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**Psoriasin Gel**

**Active ingredient**

Coal Tar 1.25% (from coal tar topical solution, USP)

**Purpose**

Psoriasis/Seborrheic Dermatitis Treatment

**Uses**

For the relief of symptoms associated with psoriasis and/or seborrheic dermatitis including itching, scaling, flaking, redness and irritation of the skin. Helps prevent recurrence.

**Warnings**

**For external use only.**

**Ask a doctor before use**

- for prolonged periods
- if condition covers a large area of the body
- around the rectum or in the genital area or groin
- with other forms of psoriasis therapy such as ultraviolet radiation or prescription drugs.

**When using this product** avoid contact with the eyes. If contact occurs, rinse eyes thoroughly with water.

**Stop use and ask a doctor if**

- condition worsens
- condition does not improve after regular use of this product as directed.

**Use caution** in exposing skin to sunlight after applying this product, as it may increase your tendency to sunburn for up to 24 hours after application.

**Warning:** This product contains chemicals known to the State of California to cause cancer.

**Keep out of reach of children.** If swallowed, get medical help or contact a poison control center right away.

**Directions**

- Read all package directions and warnings before use.
- Use only as directed.
- Apply (gently massage in) a small amount of Psoriasin Gel to affected areas.
- Apply one to four times daily or as directed by a doctor.

- Apply to thoroughly dry skin.
- The active ingredient, coal tar, in Psoriasin Gel may affect very light hair color; test first on a few strands of hair before broader application to areas where light colored hair is present.
- Wash affected area at least daily with mild soap and warm water and dry thoroughly.
- Intended for use by normally healthy adults only.
- Persons under 18 years of age or those with highly sensitive or allergic skin should use only as directed by a doctor.

## Other Information

You may report serious side effects to the phone number provided under *Questions?* below.

## Inactive ingredients

Aloe vera gel, ethanol, hydroxypropyl cellulose, isopropyl alcohol, polyethylene glycol, polysorbate 80, purified water and vitamin E acetate.

## Questions?

1-800-792-2582

## Package Insert

### Psoriasin

#### DAYTIME RELIEF VANISHING GEL

#### DERMATOLOGIST RECOMMENDED

- Stops Psoriasis itching, scaling, redness
- Can complement topical steroids
- Dries quickly, low odor
- Visible results in just days
- Helps prevent recurrence

**Psoriasin Daytime Relief Vanishing Gel** gets to work quickly to help stop the itching, flaking, redness and related discomforts associated with psoriasis. Formulated in a vanishing gel base with aloe and vitamin E, it applies easily, dries quickly and absorbs thoroughly, leaving no greasy appearance or lingering odor. Use **Psoriasin Daytime Relief Vanishing Gel** with confidence to relieve symptoms of psoriasis and help restore your skin to a more natural looking appearance.

### How Coal Tar Works

The coal tar in **Psoriasin Daytime Relief Vanishing Gel** slows down the excessive skin cell production that is the root cause of psoriasis symptoms. No other FDA compliant non-prescription drug ingredient works this way. Slowing excessive skin cell production means it can help reduce the itching, scaling and redness of psoriasis. With regular use as directed, **Psoriasin Daytime Relief Vanishing Gel** can even help prevent recurrence of psoriasis symptoms. And coal tar can be used to complement topical steroid therapies.

### The Role of Topical Steroids

Topical steroids - similar to the natural corticosteroid hormones produced by the adrenal glands - are a frequently used psoriasis symptom treatment. Topical steroids are used as anti-inflammatory agents to reduce the swelling and redness of lesions. Although topical steroids can produce rapid symptom relief, continuous use of them may cause potential side effects such as skin thinning.

## Topical Therapy Choices for Psoriasis Symptom Control

Due to the well documented side effects of topical steroids, some experts recommend using intermittent therapy (also called weekend or pulse therapy). This type of treatment involves applying a topical steroid for three consecutive days each week followed by four days of a coal tar medication like **Psoriasin Daytime Relief Vanishing Gel**. Ask your doctor if this approach might be right for you.

## PSORIASIS SELF-CARE TIPS

In addition to psoriasis treatments recommended by a doctor, you can help reduce psoriasis symptoms by using self-care approaches, including:

### Keep Skin Moisturized

Using a moisturizer is an important part of self-care for psoriasis. Dry skin makes irritation and itching caused by psoriasis worse than it needs to be. A vicious cycle can result: dry skin can cause itching and scratching, leading to new psoriasis patches developing on the irritated skin. Dermatologists recommend ointments and heavy creams to lock water into the skin.

### Bathe with Care

Too many baths and showers can dry your skin. Here are a few suggestions:

- Don't bathe or shower with hot water, which can irritate. Use lukewarm water instead.
- Don't dry off by rubbing with a towel. Pat yourself somewhat dry and then apply cream.
- Plain water can dry your skin. Adding salts, oil, or finely ground oatmeal to bath water can help to soothe your skin.
- Take fewer showers and baths. They can strip your skin of natural oils. Bathe every other day or every third day, especially during the winter months.

### Reduce Stress

Stress can cause psoriasis to flare for the first time or aggravate existing psoriasis. Relaxation and stress reduction may help prevent stress from making your psoriasis symptoms worse.

- Engage in relaxation techniques, such as yoga, meditation, or massage
- Exercise regularly
- Get enough sleep

### Be Smart About Sunlight

The ultraviolet rays in sunlight slow the growth of skin cells, so getting moderate doses of sun is good. But make it brief and use sunscreen, because sunburn can trigger psoriasis flare-ups. Some medications can make your skin more sensitive to ultraviolet rays, so talk to your doctor first.

### Stick to the Plan

Applying creams and ointments day after day can be inconvenient. But compliance is the key for topical therapies. Once you have a topical treatment regimen that's working for you, making it part of your daily routine can improve results. Also, topical therapies help you avoid the potential side effects of systemic treatments for psoriasis.

The active ingredient in **Psoriasin Daytime Relief Vanishing Gel** has been recognized to be safe and effective by an FDA Expert Advisory Panel when used as directed.

## USE THE FAMILY OF PSORIASIN PRODUCTS TO BUILD YOUR PSORIASIS TREATMENT REGIMEN:

- **PSORIASIN PROBLEM SKIN FORMULA CREAM** Combines a low dose of coal tar with botanicals & Vitamin D3 in a soothing cream that won't irritate sensitive skin
- **PSORIASIN DEEP MOISTURIZING OINTMENT** Delivers coal tar in a base that locks in moisture for hours to help restore your skin's appearance
- **PSORIASIN DAYTIME RELIEF VANISHING GEL** Is a quick-drying, low-odor coal tar

therapy

WWW.PSORIASIN.COM

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1015

**Psoriasis.**

**DAYTIME RELIEF**  
VANISHING GEL

**SOOTHES SKIN**  
Works on and in the skin for prompt and lasting symptom relief.

**CONCENTRATED**  
A small amount of the non-staining gel is all you need.

**LIGHT & EASY**  
Dries quickly & absorbs thoroughly with no lingering odor.

Coal tar has been recognized as safe and effective by the FDA, when used as directed.

DERMATOLOGIST RECOMMENDED

**Psoriasis.**

**DAYTIME RELIEF**  
VANISHING GEL

**STOPS PSORIASIS**  
ITCHING + SCALING + REDNESS

Can Complement Topical Steroids  
Dries Quickly, Low Odor  
Visible Results in Just Days

TOPICAL GEL  
NET WT 1 OZ (28.35 g)

Prod No.: 66028

Dist.: ALVA-AMCO Pharmaceutical Cos., Inc.  
Niles, IL 60714, U.S.A.  
© 2002-2015 ALVA  
® Reg. U.S. Patent & Trademark Office

\*Based on independent syndicated market research data.

LOT: EXP:

DERMATOLOGIST RECOMMENDED

**Psoriasis.**

**DAYTIME RELIEF**  
VANISHING GEL

Contains coal tar, the only FDA compliant, non-prescription drug ingredient that slows excessive skin cell production, the root cause of psoriasis symptoms.



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**Drug Facts**

**Active ingredient**  
Coal Tar 1.25% ..... Psoriasis/Seborrheic Dermatitis Treatment (from coal tar topical solution, USP)

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**Questions? 1-800-792-2582**

CONTAINS NO GLUTEN INGREDIENTS

KEEP TIGHTLY CLOSED WHEN NOT IN USE.  
STORE AWAY FROM EXCESSIVE HEAT AND COLD.

## PSORIASIN GEL

coal tar gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0295-6602
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
COAL TAR (UNII: R533ESO2EC) (COAL TAR - UNII:R533ESO2EC)	COAL TAR	12.5 mg in 1 g

### Inactive Ingredients

Ingredient Name			Strength	
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
ALCOHOL (UNII: 3K9958V90M)				
HYDROXYPROPYL CELLULOSE (TYPE M) (UNII: U3JF91U133)				
ISOPROPYL ALCOHOL (UNII: ND2M416302)				
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)				
POLYSORBATE 80 (UNII: 6OZP39ZG8H)				
WATER (UNII: 059QF0KO0R)				
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0295-6602-06	28.35 g in 1 TUBE; Type 0: Not a Combination Product	01/18/2019	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final		part358H	01/18/2019	

**Labeler** - Denison Pharmaceuticals Inc. (001207208)

Establishment			
Name	Address	ID/FEI	Business Operations
Denison Pharmaceuticals Inc.		001207208	manufacture(0295-6602)

Revised: 1/2019

Denison Pharmaceuticals Inc.